

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TENNESSEE
AT CHATTANOOGA

UNITED STATES OF AMERICA)
) 1:18-cr-11
v.)
) Judge Mattice/Steger
JERRY WAYNE WILKERSON,)
MICHAEL CHATFIELD,)
KASEY NICHOLSON,)
BILLY HINDMON, and)
JAYSON MONTGOMERY)

**GOVERNMENT'S RESPONSE TO DEFENDANTS' MOTION IN LIMINE TO
PROHIBIT TESTIMONY REGARDING MEDICAL EFFICACY**

COMES NOW the United States of America by and through J. Douglas Overbey, United States Attorney for the Eastern District of Tennessee, and Perry H. Piper and Franklin P. Clark, Assistant United States Attorneys, and hereby offer this response to the defendants' motion in limine seeking to prohibit testimony regarding the efficacy of the compounded drugs. (R. 163 and 164, Motion and Memorandum in Support.) The United States opposes the motion.

Background

An essential part of the scheme to defraud in this case involved recruiting customers to order high-priced compounded medications through the defendants. During the investigation stage, agents interviewed dozens of witnesses who ordered the medications. Some of those witnesses testified before the Grand Jury. Almost every customer interviewed was asked about the efficacy of the medications. The answers ranged from "they worked," "I couldn't tell any difference," or "they caused me problems." When asked whether the medications were worth the price paid by the insurance company, no customer ever said that he or she would pay the cost out of pocket. A few said they did not care what the insurance company paid. Most agreed that they would not have paid the amount of the co-pay for the insurance if they had been required to pay

it. Many of the customers had no idea how much the insurance companies or Tricare were being billed for the creams or medications. Some of the customers were angry that their insurers had been charged so much, even though the customer did not suffer a financial loss.

The defendants suggest that the “reality is that the creams and other medications were effective in treating patient’s conditions.” (R. 164, PageID# 785.) Also, “[a]ny assertion by the government that the compounded medications were not effective treatments in no way proves or disproves any element of any of the numerous charged crimes in this indictment.” (*Id.* at 786.) The defendants then suggest that the evidence should be excluded under Rule 403, “the probative value of such proffered evidence is nonexistent first and foremost because it isn’t true.” (*Id.*) The defendants argue that the government does not intend to call an expert witness regarding the efficacy of the creams, and suggest that any effort to do so now would be futile because of the age of the creams. (*Id.*) The defendants sum up by claiming

The prejudicial impact of such proffered evidence substantially outweighs the probative value. There is no question that the allegations regarding the effectiveness of the medication would confuse the jury, especially given that most of the allegations against the defendants involve fraud, but do not involve the medication itself being fraudulent. The admission of such evidence would mislead the jury as to the motives of the defendants. Further, given that this trial is anticipated to last three to four weeks, the government should not be permitted to needlessly waste time introducing irrelevant and inadmissible evidence relating to the medical efficacy or necessity of the medications patients were prescribed.

(*Id.* at 786-87.)

As the government has noted elsewhere, the costs of the creams/medications generally ranged from \$5,000 to \$15,000 per bottle. The customers were never informed of the cost. In fact, the customers were generally told that there would be no “out-of-pocket” expense to them. The defendants or the pharmacies would ensure that the co-pay was covered (or waived). Finally, most of the customers were offered an inducement to order the creams; they were told that they would

be participating in a study and would receive a payment for the study. Generally, the study fee paid to the customers amounted to around \$100. Sometimes, the study fee was paid for each prescription.

The relationship between the health care practitioners and the customers was suspect. The consultations generally occurred over the telephone and without any in-person contact between the health care professional and the customer. After a cursory “tele-medicine” consultation, the health care professional sent the prescription to the pharmacy to be filled. After receipt of the prescription, the pharmacy filled the prescription, sent the bill to the insurance company, received reimbursement from the insurance company (or Tricare), and then sent Wilkerson his portion of the payment (which was generally 35 to 40% of the amount billed). In turn, Wilkerson paid his “downlinks”: Chatfield, Nicholson and Hindmon. Generally, Chatfield, Nicholson and Hindmon made 50% of the amount billed under their name and sent to Wilkerson, which represented approximately 17.5 to 20% of the total amount billed to the insurance company. Defendant Montgomery was downlinked from Hindmon. Wilkerson and Hindmon each took their share of what Montgomery was able to sell.

The cost of the creams and their efficacy is relevant to the scheme to defraud. The information to be elicited is not unfairly prejudicial and is not a waste of time. If the defendants are concerned about wasting time and judicial resources, the government will prepare a summary chart showing the cost of the creams for each customer. Asking each customer to testify about whether the creams worked is not an undue burden.

ARGUMENT

I. Evidence of the efficacy of the compounded medications is relevant, probative, and admissible

The scheme to defraud in this case involved the marketing of exorbitantly priced compounded medications to customers (individuals with certain types of insurance) who had no real medical need, had no real doctor/patient relationship, and who initially were unaware that they (the customers) were the conduit to a fraudulent scheme. The insurance companies and Tricare are the victims. The defendants created and/or participated in a scheme to defraud the insurers. The defendants suggest that the “probative value of such proffered evidence is nonexistent first and foremost because it isn’t true.” (R. 164, PageID# 786.) That statement is a question for the jury and weighs in favor of admissibility.

During the investigation, customers who ordered creams were interviewed. None of the customers were initially aware of the cost of the medication. A few of them became aware of the cost because they were recruited to be marketers. Some of them claimed the creams were effective; others claimed they were not. A few suggested that the creams caused them difficulty.

Regarding the testimony of the customers, it is important to consider the circumstances. The customers were not “seeing” a health care professional, they were talking to one over the phone. All maladies are in some sense subjective; pain is particularly subjective. Who better to offer an opinion on the efficacy of the creams than the customer? The testimony by the customers will be based upon their own first-hand experience, not an expert opinion. The proof of efficacy is relevant: these drugs were not manufactured with efficacy as the target; they were manufactured with re-imbursement as the ultimate goal. Evidence is “relevant” if it “has a tendency to make a fact more or less probable than it would be without the evidence; and the fact is of consequence in determining the action.” Fed. R. Evid. 401. During the investigation, many

customers were asked how the drugs compared to others that were available over the counter, such as Ben-Gay, Oil of Olay or Gold Bond. Many gave opinions on the comparative efficacy. If a compounded drug is just as effective, or slightly more effective, than Gold Bond, then what would be the point of the compounded medications? The simple answer is this: the point of selling a cream, which may compare to an over-the-counter product, was to make money. These compounded medications were formulated and sold as part of the scheme to defraud. The efficacy of the creams is relevant.

The defendants misapprehend the nature of “lay testimony.” This is not “anecdotal evidence” in that the witnesses will be testifying as to something that happened to someone else, or something the witness heard “on the street.” It will be based upon the witness’s own personal experience. Rule 701 provides

If a witness is not testifying as an expert, testimony in the form of an opinion is limited to one that is:

- (a) rationally based on the witness’s perception;
- (b) helpful to clearly understanding the witness’s testimony or to determining a fact in issue; and
- (c) not based on scientific, technical, or other specialized knowledge within the scope of Rule 702.

Lay testimony includes “results from a process of reasoning familiar in everyday life,” whereas “an expert’s testimony results from a process of reasoning which can be mastered only by specialists in the field.” *United States v. White*, 492 F.3d 380, 401 (6th Cir. 2007)(further citations omitted). The testimony concerning the efficacy of the creams would include the rational basis for the witness’s perception, would help the jury to understand the witness’s testimony and determine a fact in issue, and would not be based upon “scientific, technical, or other specialized knowledge.” Any witness could testify regarding the effectiveness of medication, or the side-effects of it. For example, a witness might opine that an aspirin “made my headache go away,” or

Tinactin “cured my athlete’s foot.” Such an opinion does not call for medical or other specialized training; such testimony does not fall within the scope of expert opinion. This type of testimony is permissible “lay experiential expertise ... ‘founded on personal knowledge and susceptible to cross-examination.’” *United States v. Galatis*, 849 F.3d 455, 461 (1st Cir. 2017) (citing *United States v. Vega*, 813 F.3d 386, 394 (1st Cir. 2016)). It is relevant to the charged fraud, highly probative of the scope and significance of the charged fraud, and should be admitted.

II. Efficacy evidence is not unduly prejudicial

The probative value of the efficacy of the creams is strong. Most importantly, it shows the nature of the scheme and the intent to defraud that the government must prove beyond a reasonable doubt. If the cost of the creams were slight, the probative value would be lessened. If the efficacy of the creams was miraculous, and they were used to treat serious conditions, the probative value would be lessened. Neither is the case here. The cost was exorbitant and the benefit was slight or nonexistent. If the defendants believe that testimony regarding the efficacy of the creams is too damning, they may ask the Court for a special instruction. *See, e.g., United States v. Wright*, 16 F.3d 1429, 1443 (6th Cir. 1994) and *United States v. Myers*, 123 F.3d 350, 363–64 (6th Cir. 1997) (possible prejudice to defense minimized where trial court admonished jury at trial and in final instruction that other acts could only be considered for narrow purpose). The probative value of the statements is not *substantially* outweighed by their prejudicial effect. *United States v. Young*, No. 4:14-CR-64, 2014 WL 2523546, at *2 (N.D. Ohio, June 4, 2014).

In weighing the probative value of the effectiveness of the creams against the danger of unfair prejudicial effect, the government submits the probative value of this type of testimony would not be substantially outweighed by any prejudicial effect. *United States v. Sims*, 708 F.3d 832, 836 (6th Cir. 2013). The evidence the government seeks to introduce is directly probative of

the defendants' intent and motive. “[E]vidence that undermines one's defense by virtue of its 'legitimate probative force' does not unfairly prejudice the defendant.” *United States v. Censke*, 449 F. App'x 456, 467 (6th Cir. 2011) (quoting *United States v. Schrock*, 855 F.2d 327, 335 (6th Cir. 1988)). The effect of the evidence must not simply be prejudicial, but it must be “unfairly” so: “[u]nfair prejudice does not mean the damage to a defendant's case that results from the legitimate probative force of the evidence; rather it refers to evidence which tends to suggest decision on an improper basis.” *United States v. Ray*, 549 F. App'x 428, 434 (6th Cir. 2013) (citing *United States v. Bonds*, 12 F.3d 540, 567 (6th Cir. 1993)).

Conclusion

For the reasons set forth above, the defendants' motion in limine to prohibit testimony regarding the efficacy of the creams should be denied.

Respectfully submitted,

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